Exhibit B

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA,	
v.	**Criminal No: 09-CR-10330-GAO**
(1) STRYKER BIOTECH, LLC, **(2) MARK PHILIP,** **(3) WILLIAM HEPPNER,** **(4) DAVID ARD and** **(5) JEFFREY WHITAKER,**	
Defendants.	

DEFENDANTS' DISCLOSURE OF ANTICIPATED EXPERT TESTIMONY

DR. WILLIAM L. CATON III

Pursuant to Fed. R. Crim. P. 16(b)(1)(C)(i), Defendants hereby disclose a written summary of the anticipated testimony of William L. Caton III, M.D., who may be called to testify during the course of the Defendants' case at trial. Dr. Caton is an experienced neurosurgeon in private practice and affiliated with Huntington Hospital in Pasadena, California. He is a graduate of the Massachusetts Institute of Technology and the University of Southern California School of Medicine, and a former president of the California Association of Neurological Surgeons. A copy of Dr. Caton's *curriculum vitae* is attached.

If called, Dr. Caton is expected to testify as to the nature and extent of his more than thirty years' professional experience as a practicing and teaching neurosurgeon (performing approximately 350 to 400 major surgical procedures per year, and a total of more than 10,000 such procedures in his career), encompassing both intracranial and spinal surgery; that his practice in more recent years consists of approximately 85% spinal surgery, with a surgical

calendar typically including several posterolateral lumbar fusion procedures ("PLF") per week; and that he has thus performed thousands of PLF procedures over the course of his career. Dr. Caton is further expected to testify as to the various significant benefits of (*e.g.*, improved quality of life; relief from effects of spinal stenosis or spondylolisthesis; and resulting increased skeletal stability and relief from constant pain) and risks attendant to spinal surgery in general and PLF procedures in particular.

Additionally, Dr. Caton is expected to testify as to the many developments in the field of spinal surgery, especially in regard to bone grafts and PLF procedures, over the course of his professional life; that he considers the advent of bone morphogenetic proteins ("BMPs"), such as INFUSE and OP-1, to represent a significant advancement in spinal surgery; that such BMPs provide an osteogenic "growth signal" many times stronger than iliac crest graft, the prior standard of PLF care; that BMPs have played a critical role in surgical treatment of high-risk spinal cord injuries, where they constitute valuable tools for spine surgeons; and that he has had significant experience using BMPs and prefers their use over iliac crest in certain PLF surgeries. The bases for this testimony are Dr. Caton's education, training, and experience; and his significant understanding and use of BMPs generally, and INFUSE and OP-1 in particular, in his spinal surgery practice.

Dr. Caton is also expected to testify that during the relevant time period, Calstrux was one of several commercial products available for use as a bone void filler ("BVF"); that BVFs also serve a critical function in connection with PLF surgery, by providing a matrix, or "scaffold," on which new bone signaled by the BMP may grow; that the mixing of products is standard-of-care practice in spinal surgery, and particularly in the preparation of bone graft, as iliac crest, bone marrow aspirate, and BMPs can be mixed with local bone, cadaveric bone,

blood, saline, BVFs, or a number of other bone expander products; that BMPs and BVFs are known separate products; that he specifically understood that OP-1 and Calstrux were two separate products, which he often elected to mix together in the course of PLF surgical procedures, in such volume and consistency as he in his independent medical judgment saw fit; and that he found OP-1 was more likely to stay in place (*i.e.*, not to migrate) when mixed with Calstrux, thereby producing stronger and more effective bone grafts.

Dr. Caton is further expected to testify that while he then understood and continues to understand that such mixing and use of BMPs and BVFs in combination may be "off-label," he determined that such use was in the best interest of his patients, according to his obligation to exercise independent medical judgment in deciding the most appropriate manner and means of such patients' particular surgical procedures; that while the FDA has a legally mandated role to play in approving medical devices, the conditions under which devices are tested and approved must be uniform and controlled, and therefore they are not necessarily the optimal conditions for any particular patient; that he therefore bases his surgical decisions (including decisions to proceed in a non-FDA-approved, or "off-label," manner) on his own medical research into the products at issue, his professional discussions with colleagues, and his independent medical judgment in this regard; that on this basis, Dr. Caton began and continued to mix OP-1 and Calstrux in PLF surgery; and that such combination routinely resulted in successful outcomes (*i.e.*, solid bone growth resulting in relief from instability; cessation of neurological sequelae, such as tingling and numbness; and corresponding decreases in mechanical back pain) and satisfied patients.

Dr. Caton is expected to testify that mixing OP-1 and Calstrux, as above, neither alters the inherent properties of OP-1 nor leads to higher rates of infection and/or so-called "adverse

events." Dr. Caton is further expected to testify that he has not observed any adverse events in any of the spinal fusion patients in whom he implanted OP-1, based upon the approximately 100 surgeries he performed with that product, in the majority of which Dr. Caton used a mixture of OP-1 combined with Calstrux. Dr. Caton's opinions are also based on his average post-surgical infection rate of less than 1% in these procedures, which rate was the same for patients receiving either OP-1 alone or OP-1 mixed with Calstrux; his personal observation of his patients in the course of post-surgical care and treatment; and his continuing efforts to educate himself about adverse events through medical literature, hospital review committees, and professional conversations with colleagues in the greater Los Angeles area, in the Western Neurosurgical Society, and in the California Association of Neurological Surgeons.

Finally, Dr. Caton is expected to testify regarding his interactions over the years with sales representatives for medical device companies. He will describe his practice of requesting sales representatives' attendance in his operating room, and the ways in which he calls upon sales representatives to assist his surgical team, including representatives' ensuring that the surgical trays are configured to contain all those medical device products that may be called for during surgery, and identifying such products (by use of laser pointer) to the scrub tech and other operating room staff when the surgeon calls for such products in the course of the procedure; and that such assistance by sales representatives in no way alters the fact that as the primary surgeon during a case, he decides how the procedure will take place, including whether to employ one or more medical devices, and if more than one device or product are to be combined or mixed, in what manner and in what combination such products should be mixed.

Dr. Caton will also testify that he does not ask or rely on sales representatives as a source of information on the FDA-approved status of products or devices, as a source of information

about clinical studies conducted on products or devices, or as a source of information on adverse events related to products or devices; in such instances, Dr. Caton instead relies on his own medical product research, education (including the medical literature review and professional interactions with colleagues described above), training, experience, and routine practice over more than 30 years as a neurosurgeon.

Dr. Caton may offer other and further expert (fact and/or opinion) testimony in response to issues that may be raised hereafter or based on additional discovery provided by the Government, and its fact or expert witnesses, before or during trial of this matter. Correspondingly, Defendants reserve the right to supplement this disclosure as provided under Rule 16(c).

Respectfully submitted,

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